April 16, 2004

Thomas M. Mack, M.D., M.P.H.
University of Southern California School of Medicine

Dear Dr. Mack:

The purpose of this letter is to update you on the progress of the Office of Environmental Health Hazard Assessment (OEHHA) in preparing cancer hazard identification documents on each of the statin drugs. As reported at the October 17, 2003 public meeting of the Carcinogen Identification Committee, OEHHA has solicited information relevant to the assessment of the evidence of carcinogenicity of each of the statins by issuing public notices in the *California Regulatory Notice Registry* (*CRNR*) and on our Web site at www.oehha.ca.gov. Specifically, OEHHA published a Request for Information on atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, lovastatin, provastatin sodium, and simvastatin in the *CRNR* on February 21, 2003, and a Request for Information on rosuvastatin calcium in the *CRNR* on September 26, 2003.

In response to those requests, OEHHA has received information, much of it in the form of summaries or reviews of human and animal studies, on all but one of the statins (no information was submitted on cerivastatin sodium). These submissions included data from rodent studies of atorvastatin calcium and fluvastatin sodium that are not available in the published scientific literature.

OEHHA has also submitted several Freedom of Information Act (FOIA) requests to the U.S. Food and Drug Administration (FDA) on the statins. At this time, OEHHA still awaits FDA responses to FOIA requests for animal carcinogenicity studies of atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, lovastatin, and pravastatin sodium. OEHHA has recently reminded the FDA of these outstanding requests and added a request for the animal carcinogenicity studies for rosuvastatin calcium.

OEHHA continues to gather and evaluate relevant publications on the statins, including epidemiology studies and studies providing information relevant to the mechanism of action. OEHHA anticipates that draft cancer hazard identification documents on all statins will not be available for Committee consideration and deliberation until 2006 at the earliest.

Should you have any questions, please call me.

Sincerely,

Val F. Siebal
Chief Deputy Director